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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,084	08/09/2001	Gil Tenne	U 013591-0	4110
140	7590	08/23/2007		
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			EXAMINER HINES, JANA A	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 08/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/927,084	TENNE ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 36-59 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-59 and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 23, 2007 has been entered.

Amendment Entry

2. The amendment filed May 23, 2007 has been entered. Claims 1-15 and 36-41 have been withdrawn from consideration. Claims 16-35 and 60 have been cancelled. Claims 42-59 and 61-63 are under consideration in this office action.

Withdrawal of Rejections

3. The objection of claim 57 has been withdrawn in view of applicants' amendments and arguments.

Response to Arguments

4. Applicant's arguments filed May 23, 2007 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Objection and Rejection

Specification

5. The disclosure is objected to because of the following informalities:
- a) Para. [0031] in published US application 20030044881 recites "thie" instead of "the". Appropriate correction is required.
 - b) Para. [0039] in published US application 20030044881 recites "Yersmisa" instead of "Yersinia".
- Appropriate correction is required.

Claim Objections

6. Claims 56 and 57 are objected to because of the following informalities:
- a) Claim 56 lacks a period at the end of the claim. Appropriate correction is required.
 - b) Claim 57 has a period after the word "Claim.", therefore the period should be removed. Appropriate correction is required.

c) claim 57 recites "wherein said bacterial is *Streptococcus bois* and/or *Enterococcus* sp. or both." However it appears that the claim should recite the word "bacteria" instead of bacterial. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 63 is drawn to the method of Claim 62, wherein at the end of the time period, the number of interacted and/or non-interacted cancer cells present at the end or of said time period is determined.

Neither the specification nor originally presented claims provides support for the method of Claim 62, wherein at the end of the time period, the number of interacted and/or non-interacted cancer cells present at the end or of said time period is determined. Applicant did not point to support in the specification for the method of diagnosis, wherein at the end of the time period, the number of interacted and/or non-interacted cancer cells present at the end or of said time period is determined.

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Moreover, applicant failed to specifically point to the any analysis at the end of the time period wherein the number of interacted and/or non-interacted cancer cells present is determined. Thus, there appears to be no teaching of the method of diagnosis, wherein at the end of the time period, the number of interacted and/or non-interacted cancer cells present is determined. Applicant has pointed to paragraphs [0021], [0022], [0035], [0073], and [0078] and Figure 1 of the instant specification for support of the amendment, however it appears that the entire specification appears to fail to recite support for the amended claim. Paragraphs [0021], [0022] and [0035], are drawn to the preparation and interaction steps along with support for the removal of undesired contamination step. Paragraphs [0073] and [0078] are drawn to spreading bacteria on agar plates and determining the bacteria's presence. Figure 1 provides a schematic illustration of the method steps. Neither the paragraphs nor the figure provide support for at the end of the time period, the number of interacted and/or non-interacted cancer cells present at the end or of said time period is determined. Thus, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of the method of diagnosis, wherein at the end of the time period, the number of interacted and/or non-interacted cancer cells present at the end or of said time period is determined as recited by claim 63. Therefore, the claim incorporates new matter and is accordingly rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The rejection of claims 42-59 and 61-63 under 35 U.S.C. 112, second paragraph; and as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 42 (iv) recites "a second bacteria sample obtained from the other fecal sample." However the claim is unclear with regard to the second bacteria sample. Is the second bacteria sample the second feces-derived bacteria sample or another sample. Also it is unclear if the other fecal sample the second fecal sample, the second feces-derived bacteria sample or a different sample. It is unclear how this second bacterial sample is "obtained from" the other fecal sample. It is suggested that consistent terminology is used throughout the claims, to ensure clarity regarding the different sample types. Therefore clarification is required to overcome the rejection.

b) Claim 42 (iv) recites the limitation "the other fecal sample" in the claim. There is insufficient antecedent basis for this limitation in the claim. It is unclear what the other fecal sample is; i.e., whether it is the fecal sample or feces-derived bacteria sample.

c) Claim 43 (iv) recites "a different bacteria sample obtained from the additional fecal sample." However the claim is unclear with regard to the different bacteria sample. Is the different bacteria sample the first or second feces-derived bacteria sample or another sample. Also it is unclear if the additional fecal sample is the second fecal sample, the second feces-derived bacteria sample or a third sample. It is unclear how

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this different bacterial sample is "obtained from" the additional fecal sample. It is suggested that consistent terminology is used throughout the claims, to ensure clarity regarding the different sample types.

d) The term "different" in claim 43(iv) is a relative term which renders the claim indefinite. The term "different" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term "different" are unclear; for instance it is unclear what qualities make the sample different. Therefore clarification is required to overcome the rejection.

e) Claim 43 (vi) recites "the bacteria of the isolated in step v." It appears that words are missing from the claim. Therefore clarification is required to overcome the rejection.

f) Claim 49 recites "the same bacteria sample." However the claim is unclear with regard to the same bacteria sample. Is the same bacteria sample the first or second feces-derived bacteria sample or another sample. Therefore it is suggested that consistent terminology is used throughout the claims, such as "diagnostic sample" to ensure clarity regarding the different sample types.

g) Claim 53 recites "isolation from said fecal sample." However the claim is unclear since isolation of bacteria is from the feces-derived bacteria sample and not from the fecal sample. It is unclear if applicants are asserting that *E.coli* is isolated directly from the fecal sample and the other steps of claim 42 are omitted or if applicants

intend for isolation to be from the feces-derived bacteria sample. Therefore clarification is required to overcome the rejection.

h) Claim 57 recites "wherein said bacterial is *Streptococcus bois* and/or *Enterococcus* sp. or both." However it appears that the claim is redundant. The alternative phrase "and/or" implies that the bacteria is a) *Streptococcus bois*; b) *Streptococcus bois* and *Enterococcus* sp; or c) *Enterococcus* sp. Therefore the use of the word "both" is redundant because of the presence of the "and/or"

i) Claim 58 recites "isolation from said fecal sample." However the claim is unclear since isolation of bacteria is from the feces-derived bacteria sample and not from the fecal sample. It is unclear if applicants are asserting that *Enterococci* coliform is isolated directly from the fecal sample and the other steps of claim 42 are omitted or if applicants intend for isolation to be from the feces-derived bacteria sample. Therefore clarification is required to overcome the rejection.

Conclusion

9. No claims allowed. Claims 42-59 and 61-63 are free of the prior art but rejected under 112 2nd paragraph. The closest prior art is Karapetian (US Patent 5,344,762) Karapetian teaches a method for the early diagnosis of cancer wherein human feces-derived sample of bacteria is subjected to incubation with a standard culture of cancer cells for a period of time sufficient to enable the interaction between the bacteria and the cancer cells and effecting the determination. However al., Karapetian does not teach or

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suggest a process a method for diagnosis of cancer in a subject comprising the steps of: i) providing-a at least a first and second fecal sample from said subject; ii) treating said fecal samples to obtain a feces-derived bacteria samples therefrom; iii) identifying in the feces-derived bacteria samples one or more types of bacteria;-and iv) determining for each of said one or more types of bacteria its relative fraction from a total count of bacteria in said one of the feces-derived bacteria samples or in a second bacteria sample obtained from the other fecal sample; v) isolating one or more types of bacteria of said from one or both of the said feces-derived bacteria samples.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 14, 2007


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER